d) within approximately 15 to 20 minutes after the initial contact of the sample with the test strip, observing through the view window whether a line of color has appeared, indicating the presence in the test sample of *Streptococcus pneumoniae* and/or its cell-wall C-polysaccharide antigen.

53 The method of claim 52 wherein the liquid sample is of natural mammalian origin.

54 The method of claim 53 wherein the liquid same is selected from among human urine, human sputum and human spinal fluid.

REMARKS

A. The Claims

The claims in this application are 1-9 and 33-54.

The new claims have been substituted for claims 10-32 because these claims more clearly express the nature of the overall detection process sought to be covered, and its presently preferred embodiment, as well as that of the device equipped to perform the preferred embodiment of the detection process.

Some 23 claims have been cancelled and in their place 22 new claims are substituted. Of the new claims, claims 33 and 50 are independent claims; all other new claims are dependent upon claim 33 or claim 50. Applicant has previously paid for 5 independent claims and 10 claims in excess of 20. This application now contains 4 independent claims and 11 claims in excess of 20. It is accordingly understood that a further claim fee of $9.00 is owed at this time and a check covering that fee is appended.

B. The Restriction Requirement

Applicants do not contest the restriction requirement as applied to claims 1-9, which are presently retained herein pending the filing of one or more divisional application. These claims encompass Groups I-IV and VII as defined in the action.

Applicants do contest the restriction between Groups V and VI as it is presently understood.

Claims 33-49, as now constituted endeavor to make clear, consonant with the teachings of the specification that arriving at an assay as described requires all of the treatments described. Applicants believe and accordingly urge that the combination/subcombination restriction involving Groups V and VI, as set forth in the action, is no longer applicable and should be withdrawn. New claims 33-49 cover assays in varying degrees of scope, but these claims *all* require (a) preliminary extraction and purification of the antigen, coupling of the antigen to a chromatographic column, purification of antibodies to antigen specificity by passing them over the column to which the extracted and purified antigen is coupled and employing the thus purified antibodies as the essential detecting agent in assaying a liquid sample for the presence of *Streptococcus pneumoniae* cell wall C-polysaccharide antigen and/or bacteria containing it.

Claims 50-54 cover a preferred embodiment of the assay invention wherein the purified antibodies, purified according to the schema disclosed in the application, have been applied to two zones of the immunochromatic strip of a device that is sold in commerce. Applicants do not claim to have invented the device but believe they are entitled to claim the commercial

embodiment of that device, as equipped with the antibodies of their invention and thus uniquely suited to carry out the assay process on a liquid sample for the purpose of detecting infections due to *Streptococcus pneumoniae*, as in claim 50. Claim 52 covers the essence of the assay *process* as conducted with this commercially sold device, while claims 51, 53 and 54 simply cover specific features, such as the preferred label for the antibodies and certain especially preferred sample media. Applicants believe and therefore strongly urge that claims 33-54 *should* be maintained together in *one* patent document becasue they do not represent separate inventions at all, but instead represent the claiming of one invention in varying degrees of scope, and insofar as claims 50-54 are concerned, in a form necessary to permit express coverage of a valuable commercial embodiment.

The preferred embodiment of assay covered in this application represents the *first* method for diagnosing *Streptococcus pneumoniae*-caused disease states without any necessity for the attending physician to collect sputum, lung fluid, exudate friom a patient's nose or ears, or the like and have it cultured for a period of days before diagnosis of *Streptococcus pneumoniae*-induced disease can be made, to have received FDA approval and affirmative approbation from Centers for Disease Control. This preferred embodiment of assay as covered by claims 50-54 is rapid, as well as highly sensitive and specific. Because it allows accurate diagnosis of *Sreptococcus pneumoniae*-caused diseases within minutes rather than days, and the test is so easily performed that *anyone* can perform it, it is suitable for use under emergency conditions, such as during epidemics of *Streptococcus pneumoniae* caused disease when immediate diagnosis and treatment of large numbers of people is essential.

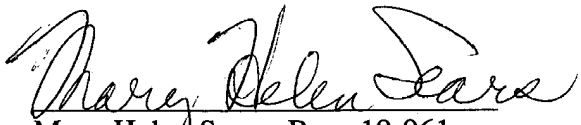
None of the assay embodiments covered in claims 33-49 or the preferred embodiment defined in terms of an assay device and specific method in claims 50-54 are suitable for any endeavor except use in the diagnosis of various *Streptococcus pneumoniae*-induced disease states. Applicants accordingly strongly urge that claims 35-54 be examined as a single unit.

To comply with the restriction requirements, Applicants provisionally elect the claims of Group V which, as Applicants' counsel understands Group V, encompass *at least* claims 33-49, for further prosecution.

Applicants traverse the restriction requirement of choosing between Groups V and VI, however, if claims 50-54 are deemed to constitute a separate Group VI. Applicants urge that claim 50 as drawn shows the need to employ *the same* "structural components" (Office Action p. 7) in every assay embodiment and that the purported distinction between Groups V and VI as combination and subcombination, which seems to have evolved from reading only the claims without the help of the disclosures, can no longer be said to exist.

To sum up, Applicants urge that claims 33-54 be examined as a unit, but provisionally elect claims 33-49 (Group V) if the Examiner persists in defining claims 50-54 as a separable invention.

Respectfully submitted,



Mary Helen Sears, Reg. 19,961
Attorney for Applicant
The M.H. Sears Law Firm Chartered
910 Seventeenth Street, N.W.
Washington, D.C. 20006
Telephone: (202) 463-3892
Telecopy: (202) 463-4852